From: Gorny, James
To: Ostroff, Stephen; Musser, Steven M; Correll, William A
Cc: Stearn, Douglas; Harris, Stic; Yiannas, Frank; Mayne, Susan; Irvin, Kari
Subject: RE: Romaine Lettuce Sample Update
Date: Thursday, December 06, 2018 9:41:02 AM

Dr. Ostroff and others,

As per your inquiry, please find below suggested strategies and tactics that have been circulating to address the Yuma situation and repeated STEC outbreaks associated with leafy greens.

1. **United Fresh / PMA / Western Growers Meeting (now set for 12/13/18):** to strongly suggest that industry take immediate actions through the existing LGMA agreements not putting things off with more task force meetings. We need all three of these trade orgs at the table to make this work and I would be happy to explain why this afternoon.
2. **Leveraging Action by States** based on the 22 *E. coli* O157:H7 cases that are closely related to the WMIDD canl and clinical isolates from the Spring 2018 foodborne illness outbreak associated with romaine lettuce consumption

Details are outlined below.

Actions available to FDA seem very limited to: 1) produce farm inspections and 2) sampling assignments. Open to other suggestions.

Best Regards,

Jim Gorny, Ph.D.
Sr. Science Advisor for Produce Safety
FDA CFSAN, Office of the Center Director
[redacted]

From: Gorny, James
Sent: Thursday, November 15, 2018 5:03 PM
To: Mayne, Susan <[redacted] Musser, Steven M ([redacted]
<[redacted]; Douglas Stearn ([redacted]
<[redacted]
Cc: Farrar, Jeff A. [redacted]; Buckner, Rebecca J ([redacted]
[redacted]; Christin, Charlotte - OC ([redacted]
[redacted]; Laura Pillsbury ([redacted]
Subject: OFVM/CFSAN Discussion Re: Enhancing the Safety of Leafy Greens

Dr. Mayne, Dr. Musser, Mr. Stearn and others,

As per our OFVM/CFSAN discussion regarding a response to the Mike Taylor / STOP letter.

Please find below my initial thoughts on a long-term strategy to address the issue.

I would anticipate that PMA/United Fresh/WG would be willing to convene a meeting for FDA to express concerns and layout expectations of industry actions. Or the meeting could be convened by for example the PEW.

FYI – A small stakeholder meeting occurred in 2005 in Washington DC after the various FDA letters were issued to the tomato and leafy greens industry (referenced in the recent FDA Letter to Leafy Greens Industry) led by Dr. Bob Brackett. United Fresh convened the meeting where Bob Brackett urged the produce industry to develop commodity specific guidance for cantaloupe, leafy greens and tomatoes. The suggestions below could be brought forward at such a meeting with the leafy greens industry. These are just my preliminary thoughts meant to serve as starting point for further discussion.

Best Regards,

Jim Gorny, Ph.D.
Sr. Science Advisor for Produce Safety
FDA CFSAN, Office of the Center Director
[redacted]

Key Leafy Greens STEC Issues

1. **Ag Water Standard Update:** As per the FDA letter to the leafy greens industry; the LGMA's should consider what was reported in the EA and work on how to enhance the microbial quality of ag water being used. The *status quo* current LGMA metric/standard is unacceptable. The LGMA's cannot cling to their generic *E. coli* monitoring standard. Reassessment and changes need to be made as this monitoring strategy failed in an epic and tragic way.
2. **Local Knowledge & Resources are Needed:** AZDA, AZDEQ and CDFA must acknowledge that their leafy greens growers have an STEC/leafy greens public health issue and they need to engage and expend resources to address it. This may include engaging other ag sectors like CAFO's, sheep and poultry operations.
3. **Surveillance & Inspections:**
    a. FDA, AZDA and CDFA need to consider doing on farm inspections ASAP outside the LGMA audit system.
    b. Blitz leafy greens surveillance sampling assignment need to be issued ASAP.
4. **Provenance Labeling:** The leafy greens industry needs to develop and implement a means of identifying the provenance or origin of leafy greens products forward in the supply chain; not simply where a farm/firm is

headquartered; so as to facilitate traceback during a foodborne illness outbreaks.

5. **Root Cause Analysis**: The leafy greens industry needs to develop a turn key means to embark upon root cause analysis whenever a field of leafy greens tests positive (pre-harvest) or finished product testing (RACs or fresh-cut) tests positive for the presence of human pathogens. Associated meta data with the aim of determining the likely contributing factors that led to contamination should also be collected. This must funded by industry to have a clearinghouse of big data and a ready assembled root cause analysis team ready to engage in short timeframes. This could be done by CPS or via LGMA funds.
6. **Research**: Leafy greens growers and fresh-cut processor via pre-harvest testing, associated meta data analysis and root cause analysis have important leading hypotheses regarding likely potential contributing factors that need to be fully investigated (e.g. contamination of heat treated chicken pellets, prevalence of human pathogens in various crops, human pathogen prevalence by irrigation district/canal). These leading hypotheses need to shared with researchers so that researchers can validate or refute these leading hypotheses regarding likely contributing factors associated with contamination of leafy greens. Industry needs to inform and fund this research.
7. **Water Treatments**:
    a. **Validation**: A standardized means to validate water treatment systems using commonly use ag water disinfectants (e.g. NaOCl, Calcium Hypochlorite & ClO2) is needed. This development of this validation protocol could be done at CFSAN ORS, IFSH or funded by CPS. Key process variables around the use of such treatments would also have to be defined during the validation studies (e.g. maximum turbidity, total or suspended soluble solids and other key variable that effect human pathogen kill rates) parameters around the use of these ag water disinfectants. This means of validation could then be used by chemical suppliers to get U.S. EPA and Cal EPA approved use status to eliminate human pathogens in ag water at the urging of leafy greens growers and their trade orgs.
    b. **Short-Term:**

        i. The industry and/or FDA needs to consider an emergency request for allowed use of some ag water disinfectant chemicals by U.S. EPA and Cal EPA for specific scenario's.

        ii. Determine if other labeled use rates (e.g. for microbial potability) may be recommended by the LGMA's for use to assist with human pathogens control uses.

8. **Validation & Verification:** The AZ and CA LGMA should consider expanding audits outside of just leafy greens farms to suppliers of key leafy greens production inputs, for example of heat treated chicken pellet manufacturers. The intent would be to assure that validated and verified processes are being used; possibly even sampling materials and assuring that post processing contamination is not occurring. This would be a big value-added operation for LGMA members whom simply cannot conduct such audits and now rely on letters of guarantee regarding the inputs that they purchase.

From: Gorny, James
Sent: Friday, November 30, 2018 6:27 PM
To: Irvin, Kari <[redacted]
Cc: Harris, Stic <[redacted]; Farrar, Jeff A. <[redacted]
Subject: RE: Thoughts...WGS E. coli O157:H7 Matches to Spring 2018 Yuma Canal & Clinical Isolates

Kari, Stic & Jeff,

CDC has identified no food vehicle associated with the 22 *E. coli* O157:H7 cases that match the WMIDD and clinical isolates from the Spring 2018 foodborne illness outbreak associated with romaine lettuce consumption.

What do we do with this information to protect public health?

- **Leafy Greens Industry Outreach:** A call to the produce/leafy greens industry at this time with no definitive food vehicle or actionable recommendations would likely not be productive.
- **AZ DEQ, AZPH, AZDA:** I would suggest for consideration a call next week Wednesday after and update by CDC & FDA (highest level possible) to inform them:
  - Inform them of the findings (CDC).
  - Explain why the epi did could not identify the likely food vehicle.
  - I would characterize this as a "near miss" and that they should strongly consider taking action as in indicated in the FDA letter they received as the fact of the matter is that **CDC did find this closely strain in the WMIDD canal!**
  - While this was a "near miss" it points out the problem isn't fixed and this significantly heightens the probability of another devastating STEC foodborne illness caused by this environmental source.
  - They have an environmental issue and they should consider getting to the bottom of it and fix it.
- Outcomes
  - AZDA, AZDEQ and AZPH will likely contend that CDC identified the wrong food vehicle in Spring 2018. Sorry but the fact remains that **CDC did find this closely strain in the WMIDD canal!** The State agency's have the statutory authority and obligation to address this converged environmental, public health and agricultural economic sustainability issue. FDA does regulate the WMIDD.
  - AZDA, AZDEQ and AZPH will likely inform the leafy greens industry and this will cause great consternation. FDA could utilize this information to again urge industry to implement all the things that were discussed at the CDFA meeting of 11/28/18 in Anaheim.
    - **Local Engagement:** AZDA & AZDEQ should engage and expend resources to address it including engaging other ag sectors like CAFO's, sheep and poultry operations.

- **Ag Water Standard Update:** Reconsider AZ LGMA ag water standard using generic *E. coli* as the analyte.
- **Ag Water Treatments**:
  - Validation of ag water treatment protocols
  - Consider an emergency request for allowed use of some ag water disinfectant chemicals by U.S.
- **Ag Input Validation & Verification of Soil Amendment Inputs:** The AZ and CA LGMA should consider expanding audits outside of just leafy greens farms to suppliers of key leafy greens production inputs, for example of heat treated chicken pellet manufacturers. The intent would be to assure that validated and verified processes are being used; possibly even sampling materials and assuring that post processing contamination is not occurring.
- **Mandatory Pre-Harvest Pathogen Testing & Root Cause Analysis**: The leafy greens industry should strongly consider mandatory pre-harvest testing for LGMA members and develop a turn key means to embark upon root cause analysis whenever a field of leafy greens tests positive (pre-harvest) or finished product testing (RACs or fresh-cut) tests positive for the presence of human pathogens.
- **Research:** Leading hypotheses regarding likely potential contributing factors associated with pre-harvest sample positive results need to be shared with researchers so that researchers can validate or refute these leading hypotheses regarding likely contributing factors associated with contamination of leafy greens. Industry needs to inform and fund this research.
- **Provenance Labeling**: The leafy greens industry needs to develop and implement a means of identifying the provenance or origin of all leafy greens products forward in the supply chain; not simply where a farm/firm is headquartered; so as to facilitate traceback during a foodborne illness outbreaks.

They should urged by FDA and CDC Sr. Leadership to clean up their own backyard before a public health disaster happens again.

No action needed today but food for thought over the weekend.

Please share your thoughts on how to best use this valuable information because time is of the essence, and we are at a highly teachable moment.

Best Regards,

Jim Gorny, Ph.D.
Sr. Science Advisor for Produce Safety

FDA CFSAN, Office of the Center Director
[redacted]

From: Ostroff, Stephen
Sent: Thursday, December 6, 2018 9:18 AM
To: Musser, Steven M <[redacted]>; Correll, William A
[redacted]
Cc: Gorny, James [redacted]; Stearn, Douglas <[redacted]
Harris, Stic <[redacted] Yiannas, Frank [redacted] Mayne, Susan
[redacted]
Subject: RE: Romaine Lettuce Sample Update

There has to be a decision about what we're going to do and then we just have to do it before we're too far into the season to do anything. Isn't this supposed to be the role of the Produce Coordinating Group (led by Jim Gorny).

From: Musser, Steven M
Sent: Thursday, December 06, 2018 9:11 AM
To: Correll, William A <[redacted]>; Ostroff, Stephen
[redacted]
Cc: Gorny, James [redacted], Stearn, Douglas [redacted]
Harris, Stic <[redacted]
Subject: Re: Romaine Lettuce Sample Update

Bill,

It's very hard to say. We had another meeting with the Yuma fresh produce group yesterday (approx.. 100 people) to discuss potential research in that area. In general, I would say there is considerable irritation at pretty much everything we do. Based on yesterday's meeting, I can confirm two things. First, no one wants to see ORA show-up for on-farm investigations. There are a couple of reasons for this, that we should discuss, but suffice it to say farmers/ranchers believe the outcome will be that no one will buy from them, even if nothing is found. The second item regards sampling. While people are not really happy about sampling at coolers, if we have to sample, it is the preferred approach over in-field or retail bagged products.

Steve

From: William Correll <[redacted]
Date: Thursday, December 6, 2018 at 7:56 AM
To: "Ostroff, Stephen" [redacted]

Cc: "Gorny, James" [redacted] "Stearn, Douglas" [redacted] "Musser, Steven M" [redacted] "Harris, Stic" [redacted]
Subject: FW: Romaine Lettuce Sample Update

Steve:

I believe this CORE investigation is the likely source of the industry's lettuce rumors you inquired about.

The targeted hydro-cooler sampling in Imperial/Yuma has not yet begun. We did do SME limited targeted sampling at a couple locations in CA - results were negative on those. At the request of Center leadership, we have put the surveillance sampling of packaged mixed greens on abeyance.

Bill

From: Rogers, Michael <[redacted]
Date: November 30, 2018 at 1:14:58 PM EST
To: Correll, William A <[redacted] Givens, Joann [redacted]
Cc: Gorny, James <[redacted], Bass, Glenn <[redacted], Bromley Jr, Gerald D <[redacted]
Subject: FW: Romaine Lettuce Sample Update

FYI It looks like we have a few CROs in progress

Michael C. Rogers, MS
Assistant Commissioner for Human and Animal Food Operations
FDA/ORA/OHAFO
240-402-4029

From: Norris, Paul E.
Sent: Friday, November 30, 2018 10:42 AM
To: Rogers, Michael <[redacted]
Subject: FW: Romaine Lettuce Sample Update

Michael – Attached is the latest laboratory result update.

Paul

From: McConnell, Terri
Sent: Thursday, November 29, 2018 5:05 PM
To: CORE Response Team 1 <[redacted]>

Cc: Norris, Paul E. <[redacted]>; Rice, Daniel <[redacted]>; Kreuzer, Karen S <[redacted]>; Hall, Gina M <[redacted]>
Subject: FW: Romaine Lettuce Sample Update

All,

The updated sample tracking spreadsheet for the E. coli O157/Romaine (suspect)/Nov 2018 CORE event is attached. No E. coli O157:H7 has been detected in any samples analyzed to date-this includes the samples that PSFFL received yesterday morning (fish emulsion, cooler swabs, drag swabs, and romaine hearts). There are two samples that are CRO for STEC and confirmation analysis is ongoing for those samples.

If you have any questions or need additional information, please don't hesitate to contact Gina Hall or me.

Thanks!

Terri

CDR Terri T. McConnell, USPHS
FDA, ORA, Office of Regulatory Science
OFFLO Microbiology Staff Director
[redacted]

From: Hall, Gina M
Sent: Thursday, November 29, 2018 5:41 PM
To: McConnell, Terri <[redacted]>
Subject: Romaine Lettuce Sample Update

Hi Terri,

Here is the updated info.

All the samples analyzed to date are negative for E. coli O157:H7.
Samples 1020345 and 1091913 are CRO for STEC.

Please see the attached updated spreadsheet and let me know if you have nay questions.

Thank you,
Gina

Gina Hall
Microbiology Team Lead
U.S Food & Drug Administration
[redacted]